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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/011,910	02/17/1998	SERGIO ABRIGNANI	0336.001	1499

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Rebecca M. Hale, Esq
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916

EXAMINER	
WORTMAN, DONNA C	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/011,910	ABRIGNANI, SERGIO	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears n th cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2003; 21 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,7-10,17 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22 and 23* is/are allowed.

6)☒ Claim(s) *3,4,7-10,17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 November 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. With the receipt on July 21, 2003, of the signed copy of the Preliminary Amendment originally filed April 8, 2003, Applicant's submission filed on April 8, 2003, has been entered.

By entry of the amendment, the title has been changed, claims 4, 10, and 17 have been amended, and claims 21-23 have been added. Claims 3, 4, 7-10, 17 and 21-23 are pending and under examination. Claim 4 is drawn to a process of preparing a protein of molecular weight of about 24kd that specifically binds to HCV E2 protein, or a functionally equivalent fragment of the protein, where "functionally equivalent" means that the fragment specifically binds to HCV E2 protein, comprising contacting cells with a preparation of E2, obtaining a membrane preparation from cells that bind E2, and purifying the protein from the membrane preparation; claims 3 and 7-9 depend from claim 4. Claim 10 is drawn to a process of preparing a protein of about 24kd that specifically binds to the E2 protein of HCV, or a functionally equivalent fragment of the protein, comprising contacting mammalian cells with a preparation of E2 in step i), obtaining a membrane preparation from cells selected for binding to E2 in step ii), treating the preparation with ammonium sulphate in two separate steps iii) and iv), resuspending the precipitate from the second step in buffer and subjecting the

resuspended precipitate to hydrophobic interaction chromatography in step v). Claim 17 is drawn to a diagnostic kit comprising a protein having a molecular weight of about 24kd that specifically binds HCV E2, or a functionally equivalent fragment of the protein. Claim 21 is drawn to a method for preparing a protein of about 24kd or a functionally equivalent fragment of the protein comprising obtaining a membrane preparation from cells that bind to E2 and purifying the protein from the preparation. Claim 22 is drawn to a method for preparing a protein of about 24kd that specifically binds to HCV E2 comprising obtaining a membrane preparation from cells that bind to E2 in step i), treating the preparation with ammonium sulphate in two separate steps ii) and iii), resuspending the precipitate from the second step in buffer and subjecting the resuspended precipitate to hydrophobic interaction chromatography in step iv), and recovering the protein in step v). Claim 23 depends from claim 22 and recites that the cells are MOLT-4 cells.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because it recites "A method of preparation of a protein ... or for the preparation of a functionally equivalent fragment thereof" but does not recite a final step that would result in the preparation of the functionally equivalent fragment.

Claims 7-9 are indefinite as each depends alternatively from "any one of claims 2-4"; claim 2 was previously canceled.

Claim 10 is indefinite because it recites "A process for preparation of a protein of about 24kd that specifically binds to the E2 protein of HCV, or a functionally equivalent fragment of the protein," but does not recite a final step that actually results in the preparation of the protein or the fragment.

Applicant is cautioned against the introduction of new matter in amending the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. 1991 (The Journal of Biological Chemistry 266(22):14597-14602, 1991), cited on PTO 892, taken in light of Levy et al. 1998 (Annu. Rev. Immunol. 16:89-109, 1998), of record, and Pileri et al. (Science 282:938-941, 1998), cited on PTO 892. Levy et al. 1991 disclose the preparation of the human membrane protein TAPA-1, also known as CD81 (as evidenced by Levy et al. 1998), which is the same protein as Applicant's protein of about 24kD. The preparation of human TAPA-1 from cells, including human cells, anticipates the subject matter of claim 21, since the ability of human TAPA-1 and cells expressing human TAPA-1 to bind HCV E2 is inherent (see Pileri et al.), and the process steps recited in claim 21 are no different from the methods disclosed by Levy et

al. 1991 for preparing TAPA-1 (see page 14597, col. 1, first paragraph-col. 2, "Cell labeling and Immunoprecipitation"; Fig. 2; and Fig. 3, for example).

Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by Levy et al. 1991, taken in light of Levy et al. 1998, and Pileri et al., cited above. The disclosure of Levy et al. 1991 of TAPA-1 anticipates the subject matter of claim 17, since "kit" as recited is interpreted as no different from a composition comprising a protein having a molecular weight of about 24kd that specifically binds HCV E2; since Applicant's protein is the protein also known as TAPA-1 or CD81; since the ability of TAPA-1/CD81 to bind HCV E2 is inherent; and since "diagnostic" represents intended use and does not impart any structural difference to the composition as recited in claim 17.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 17 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. 1991, interpreted in light of Levy et al. 1998 and Pileri et al., cited above. Levy discloses that TAPA-1 is important in regulating cell growth (page 14597, line 1) and that the protein was identified by an assay involving cell growth as being the target of an antiproliferative antibody. A kit comprising TAPA-1, which is the same as Applicant's protein having a molecular weight of about 24kd, as evidenced by Levy et al. 1998 and Pileri et al., would have been obvious over Levy et al. 1991 because Levy et al. establish interest in and uses for the TAPA-1 protein, and because packaging reagents in the form of a kit is conventionally done for reasons of convenience and economy.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22 and 24-29 of

copending Application No. 09/755251. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 17 is drawn to a (kit) composition comprising the same protein as the protein recited in claims 22 and 24-29 of Application No. 09/755251. The composition of claim 17 is not distinguished from the protein and compositions of claims 22 and 24-29 of Application No. 09/755251 since the protein and the compositions are the same regardless of their intended use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 22 and 23 are allowed. The prior art does not teach or fairly suggest a method for purifying a protein having a molecular weight of about 24 kd which specifically binds to the E2 protein of hepatitis C virus comprising all the process steps recited in claim 22.

Claims 3, 4, 7-9 and 10 are free of the prior art and would be allowable if amended to overcome the rejections under 35 USC 112, second paragraph, set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
July 29, 2003